NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA NEUROSCIENCE, INC., ET AL. Plaintiff, v. WATSON PHARMA, INC., ET AL. Defendant.	Civil Action No. 10-5078 (CCC)(JAD) Civil Action No. 11-3076 (CCC)(JAD) CONSOLIDATED **OPINION**

CECCHI, U.S.D.J.

INTRODUCTION

This matter comes before the Court by complaint of Teva Neuroscience, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. (collectively, "Teva") against Orchid,[1] Watson,[2] Mylan[3] and Apotex[4] (collectively, "Defendants"). This case concerns the validity, enforceability and alleged infringement of United States Patent No. 5,453,446 ("the '446 Patent"), which is alleged to cover Azilect®, Teva's rasagiline mesylate tablet product. Trial is scheduled to commence on May 15, 2013. Presently before the Court are Defendants' motions *in limine* to preclude the introduction of certain evidence at trial. Having considered all

[1] "Orchid" consists of Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare (a division of Orchid Chemicals & Pharmaceuticals Ltd.) and Orgenus Pharma Inc. On April 30, 2013, the Court entered a stipulation of dismissal between Orchid and Plaintiffs. Accordingly, Orchid is no longer a party to this action.
[2] "Watson" consists of Watson Pharma and Watson Laboratories, Inc.
[3] "Mylan" consists of Mylan Pharmaceuticals, Inc., Mylan Inc. and Mylan LLC.
[4] "Apotex" consists of Apotex Corp. and Apotex Inc.

of the submissions filed in connection with the motions, the decision of this Court is set forth below.

DISCUSSION

I. Defendants' motion *in limine* to preclude Teva from presenting evidence on pharmaceutical development and difficulties

In their first motion *in limine*, Defendants seek to preclude Teva from presenting two categories of evidence. First, Defendants move to exclude Teva's proposed testimony regarding the difficulties a person of ordinary skill in the art ("POSA") would have encountered when separating the enantiomers of racemic PAI. According to Defendants, any such evidence would be inconsistent with Teva's position during the claim construction process. In response, Teva asserts that its position in this regard is not at odds with its presentation during claim construction, where the parties' disputed the purity level of R(+) PAI as described in the '446 patent. As such, Teva contends that it should be permitted to present limited evidence regarding the difficulties it had separating the enantiomers of racemic PAI, coupled with testimony regarding what a POSA would have known about such difficulties in January 1990.

Defendants' motion further seeks to preclude Teva from presenting evidence regarding the pharmaceutical development process in general or issues related to the development of Azilect® which occurred after January 3, 1990, the earliest possible priority date of the '446 patent. Defendants argue that such evidence is irrelevant and prejudicial, and should be precluded pursuant to Federal Rules of Evidence 401, 402 and 403. In opposing Defendants' motion, Teva contends that evidence regarding uncertainties in the drug development process is relevant to the obviousness inquiry in that it goes to whether or not a POSA would have a reasonable expectation of success. Teva further asserts that brief testimony regarding the

challenges it faced in developing Azilect® as a commercial product is likewise relevant to provide context for the obviousness inquiry.

Having reviewed the parties' submissions, the Court does not find grounds to preclude either category of evidence. As to the difficulties a POSA may have experienced or understood regarding separating the enantiomers of racemic PAI, the Court does not find such testimony to be categorically inconsistent with Teva's position during claim construction, where the parties disputed the purity level such separation would produce. Further, the evidence Teva intends to offer regarding the difficulty, expense and unpredictability of enantiomer separation is relevant to the Court's obviousness analysis, including a POSA's motivations or reasonable expectation of success. Indeed, the unpredictability of enantiomer separation has been specifically acknowledged by district courts, see, e.g., Forest Labs, Inc. v. Ivax Pharm., Inc., 438 F.Supp.2d 479, 493 (D. Del. 2006), *aff'd* 501 F.3d 1263 (Fed. Cir. 2007), and the Federal Circuit has stated that "predictability is a vital consideration in the obviousness analysis." Otsuka Pharm Co. v. Sandoz, Inc., 678 F.3d 1280, 1298 (Fed. Cir. 2012) (citations omitted). Accordingly, Teva will be permitted to present such evidence.

As to the second prong of Defendants' motion, "[n]either the common practice of pharmaceutical companies, nor the procedure necessary for FDA approval can be considered irrelevant to the factual underpinnings required to demonstrate obviousness or non-obviousness." Novartis Pharms. Corp. v. Teva Pharms. USA, Inc., No. 05-1887 (DMC), 2009 U.S. Dist. LEXIS 103104, at *41 (D.N.J. Nov. 5, 2009). Such evidence will assist the factfinder in understanding the relevant background and rendering a determination as to whether or not the '446 patent was obvious in light of the prior art. Similarly, Teva's proposed testimony on the challenges it faced in commercializing Azilect® may provide context for the Court's obviousness analysis. See In

re Gabapentin Patent Litig., No. 00-2931 (FSH), 2011 U.S. Dist. LEXIS 51130 at *43-44 (D.N.J. May 11, 2011) ("Evidence of the research and development efforts made in developing [a drug] are also relevant to the patent's validity."). Accordingly, Defendants' motion *in limine* No. 1 is denied.

II. Defendants' motion *in limine* to preclude Dr. Peter Jenner from offering testimony as to the state of the art

Defendants' second motion *in limine* requests an order precluding Teva's expert, Dr. Peter Jenner, from testifying as to the state of the art regarding Parkinson's disease in 1990 because he offered limited answers to six questions during his full-day of deposition testimony. In responding to those six background questions, Dr. Jenner cited confidentiality restrictions imposed by the pharmaceutical companies that sponsored his work developing new compounds to treat Parkinson's disease prior to 1990. Defendants assert that Dr. Jenner's invocation of confidentiality prevented them from fully exploring his experience with the prior art, rendering his testimony in that regard unfairly prejudicial pursuant to Federal Rule of Evidence 403.

In response, Teva counters that Defendants will not be prejudiced because they have full access to the published references Dr. Jenner utilized to reach his opinions and that he in no way relied on the confidential work cited during his deposition. Teva further contends that Defendants waived their right to object to Dr. Jenner's testimony because they delayed until the filing of the instant motion to raise it with the Court. Lastly, Teva points out that the complete exclusion of an expert is an extreme remedy that is not justified on the facts presented here.

The Court finds that exclusion of Dr. Jenner's testimony is not warranted. Contrary to Defendants' assertions, it appears that Dr. Jenner's opinion regarding the state of the art – more specifically, which chemical entity a POSA would have selected as a lead compound – is based on publicly available prior art, not unpublished research performed by Dr. Jenner. As noted by

Teva, Dr. Jenner has identified numerous prior art references which form the basis for his opinion. Defendants have not pointed to any specific statement within Dr. Jenner's report which indicates that he relied on his confidential work in forming his opinions. Accordingly, Dr. Jenner has provided substantial information concerning the basis of his opinion, despite his inability to answer certain questions based on confidentiality.

Indeed, it does appear that Dr. Jenner provided information in response to most of the six questions at issue and that he satisfactorily answered hundreds of questions regarding his opinions during his deposition, which lasted for one full day. In light of the various prior art references cited in his expert report, coupled with his lengthy deposition testimony, Dr. Jenner has provided sufficient information for Defendants to determine how he arrived at his opinion. Fitz, Inc. v. Ralph Wilson Plastics Co., 184 F.R.D. 532, 537-539 (D.N.J. 1999). Thus, allowing his testimony will not serve to prejudice Defendants. See id.

Moreover, the exclusion of testimony is a drastic remedy that is typically inappropriate absent bad faith or prejudice that cannot be cured. See Fitz, 184 F.R.D. at 536 (citing ABB Air Preheater v. Regenerative Envtl. Equip. Co., 167 F.R.D. 668, 671-672 (3d Cir. 1996); Canterna v. United States, 319 Fed. Appx. 93, 98 (3d Cir. 2008); Taylor v. Amcor Flexibles, Inc., No. 07-3477 (NLH), 2011 U.S. Dist. LEXIS 70671, at *8 (D.N.J. June 29, 2011). Here, Defendants have not shown that Teva acted in bad faith. Likewise, Defendants have not demonstrated prejudice inasmuch as Dr. Jenner may be questioned on the publicly available information referenced in his report which forms the basis for his opinion.

The Court is also constrained to note that the exclusion of Dr. Jenner's testimony is even more inappropriate given Defendants' failure to raise this issue with the Court at an earlier time. Defendants did not object to Dr. Jenner's invocation of confidentiality either during his

deposition or in motion practice with the Court after the deposition had concluded. At this late stage of the litigation, on the eve of trial, Teva would be unfairly prejudiced if it were forced to find a replacement for Dr. Jenner on such short notice. Accordingly, Defendants' motion *in limine* No. 2 is denied.

III. Defendants' motion *in limine* to exclude the testimony of Dr. Henchcliffe

In their third motion *in limine*, Defendants move pursuant to Federal Rules of Evidence 403 and 702 and Daubert v. Merrill Dow Pharms. Inc., 509 U.S. 579, 589 (1993) to preclude Teva from presenting testimony from Dr. Claire Henchcliffe regarding certain secondary considerations of non-obviousness. Defendants anticipate that Dr. Henchcliffe will offer rebuttal testimony on the clinical benefits associated with Azilect®, which Teva relies on, in part, to demonstrate that the '446 Patent is not obvious. Defendants argue that Dr. Henchcliffe's testimony should be excluded as irrelevant and unreliable under Rules 403 and 702 because: (1) she was not a POSA in 1990; and (2) she did not meaningfully compare Azilect® to the prior art, but instead discussed data comparing Azilect® to a placebo. In response, Teva contends that Dr. Henchcliffe is more than qualified to serve as an expert at trial and states that there is no requirement that an expert be a POSA in order to provide testimony on obviousness. Teva further counters that Dr. Henchcliffe did indeed provide a meaningful comparison of Azilect® to the prior art that may assist the trier of fact regarding secondary considerations of non-obviousness.

Secondary considerations of non-obviousness must be considered by the Court in the obviousness inquiry and serve the important function of "guard[ing] against hindsight bias." In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Litig., 676 F.3d 1063, 1079 (Fed. Cir. 2012). Such secondary considerations include unexpected results, commercial success,

copying, licenses, long-standing yet unsatisfied need and failures of others to solve the problem addressed by the invention. Graham v. John Deere Co., 383 U.S. 1, 17 -18 (1996). In the instant matter, Dr. Henchcliffe's testimony will be offered by Teva to address secondary considerations of non-obviousness, including long-felt need.

Having reviewed Dr. Henchcliffe's credentials, the Court finds her to be qualified and her testimony to be relevant and reliable within the meaning of Rules 403 and 702. As an initial matter, the Court notes that the relevant inquiry regarding whether an expert should be allowed to provide testimony at trial is not whether she is a POSA, but instead is grounded in whether the expert's "knowledge, skill, experience, training [and] education … [i]s likely to assist the trier of fact to understand the evidence." S.E.B. S.A. v. Montgomery Ward & Co., 594 F.3d 1360, 1373 (Fed. Cir. 2010); see also Mytee Prods. v. Harris Research, Inc., 439 Fed. Appx. 882, 887 (Fed. Cir. 2011) (upholding denial of motion *in limine* to exclude expert on the basis that he was not a POSA). Thus, many district courts have rejected the "remarkable proposition that only those who were skilled in the art at the time of the invention may be qualified to offer opinions on the issue of obviousness." Cardiac Pacemakers, Inc. v. St. Judge Med., Inc., No. 96-1718, 2002 U.S. Dist. LEXIS 4000, at *126-127 (S.D. Ind. Feb. 13, 2002), *aff'd in part, modified in part on other grounds*, 381 F. 3d 1371 (Fed. Cir. 2004); see also eSpeed, Inc. v. Brokertec USA, L.L.C., 404 F.Supp.2d 575, 579-581 (D. Del. 2005); Intex Recreation Corp. v. Metalast, S.A., 245 F.Supp.2d 65, 76-77 (D.D.C. 2003).

Dr. Henchcliffe's qualifications – which are undisputed – include a Ph.D. in molecular and cell biology from Oxford University and an M.D. from the College of Physicians and Surgeons at Columbia University. Dr. Henchcliffe completed a residency in neurology and a clinical fellowship in movement disorders at Columbia-Presbyterian Hospital. In addition to

lecturing extensively on Parkinson's disease, Dr. Henchcliffe is a practicing neurologist at Weill Cornell Medical Center and has served as the Director of the Weill Cornell Parkinson's Disease and Movement Disorders Institute for the last ten years. In light of these qualifications, whether or not Dr. Henchcliffe meets the definition of a POSA does not impact her ability to provide relevant expert testimony on long-felt need and other secondary considerations through her discussion of the clinical trials of Azilect®.

Further, Dr. Henchcliffe's expert report adequately discusses the prior art, including deprenyl, to address Defendants' argument to exclude her on this basis. Likewise, Dr. Henchcliffe's testimony on post-filing developments is sufficient to provide relevant testimony that may assist the factfinder on secondary considerations of non-obviousness. See Knoll Pharm. Co. v. Teva Pharms. USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004) ("[E]vidence developed after the patent grant is not excluded from consideration …"); Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc., 655 F.3d 1291, 1307 (Fed. Cir. 2011) ("evidence of unexpected results may be used … even if that evidence was obtained after the patent's filing or issue date."). Finally, the Court does not find Dr. Henchcliffe's opinion to be irrelevant merely because the clinical trials on which she relies compare Azilect® to a placebo. See, e.g., Sanofi-Aventis Deutschland GmBH v. Glenmark Pharms., Inc., USA, No. 97-5855 (DMC), 2011 U.S. Dist. LEXIS 10512, at *25 (D.N.J. Feb. 3, 2011) (stating that "… there is no rule that requires comparisons to be made head-to-head"). Accordingly, Defendants' motion *in limine* No. 3 is denied.

IV. Defendants' motion *in limine* to preclude the testimony of Dr. Amos B. Smith

In their fourth motion *in limine*, Defendants move, pursuant to Federal Rules of Evidence 403 and 702, and Daubert v. Merrill Dow Pharms. Inc., 509 U.S. at 589, to exclude testimony

and exhibits from Dr. Amos B. Smith because he may not meet the definition of a POSA. In response, Teva counters that Dr. Smith is a qualified expert in stereochemistry, the area of science implicated in the '446 Patent, and that the caselaw clearly counsels against excluding an expert simply because he may not be a POSA. As such, Teva argues that Dr. Smith should be allowed to offer limited testimony at trial which provides a background tutorial on stereochemistry and his opinion regarding certain properties of R(+) PAI.

Like Dr. Henchcliffe, the Court will permit Dr. Smith to testify at trial. As set forth above, the Federal Circuit has held that the touchstone of whether an expert's testimony is admissible is not whether that expert qualifies as a POSA, but rather is whether the expert's "knowledge, skill, experience, training, [and] education … [i]s likely to assist the trier of fact to understand the evidence." SEB S.A., 594 F.3d at 1371. Dr. Smith has been a Professor in the Department of Chemistry at the University of Pennsylvania since 1981, serving as its Chairman from 1988-1996. Dr. Smith has held visiting professorships at leading universities around the world, including Cambridge University. Dr. Smith's work has focused on the synthesis of complex organic molecules and the development of new pharmaceutical products. Through that work, Dr. Smith has developed experience in stereochemistry and stereochemical effects on the biological and pharmacological activity of organic compounds. In particular, Dr. Smith has significant knowledge of the differences between enantiomers and the racemic compound from which they are derived.

In light of his expertise in stereochemistry, the Court finds that Dr. Smith's testimony, including that related to stereochemistry and the characteristics of R(+)PAI, will assist the trier of fact. See Mytee, 439 Fed. Appx. at 886-887 (upholding district court's refusal to exclude a qualified expert who was not a POSA). Defendants' challenge to Dr. Smith's qualifications does

not render his opinion wholly inadmissible, but rather - like all admitted experts - may be an appropriate subject for cross-examination and argument regarding the weight to be given to his testimony, which the Court takes no position on at this time. Accordingly, Defendants' motion *in limine* No. 4 is denied.

CONCLUSION

For the reasons set forth above, Defendants' motions *in limine* Nos. 1-4 are denied. An appropriate Order accompanies this Opinion.

Dated: May 10, 2013

s/ Claire C. Cecchi
HON. CLAIRE C. CECCHI
United States District Judge